OPI: POS/IMP/IO

USE OF SAMPLE SEALS FOR PROGRAM SAMPLES AND OTHER APPLICATIONS

I. PURPOSE

This directive establishes policy and procedures to be followed by Program personnel for the use of official sample seals for securing samples, test agar plates, and devices such as incubators, within or outside establishments. Security seals are intended to guard against tampering and to ensure the integrity of the sealed items or samples.

II. CANCELLATION

FSIS Directive 7355.1, dated 2/4/88

II. REASON FOR REISSUANCE

To clarify inspection program employees' responsibilities regarding sample collection and integrity.

IV. REFERENCES

FSIS Directive 8150.1, Rev.1, dated 4/5/90
FSIS Directive 8410.1, Rev.1, dated 8/28/91
FSIS Directive 10,600.2,. dated 8/14/84
FSIS Directive 10,610.1, dated 3/10/86
FSIS Directive 10,620.1, Rev.2, dated 11/7/89
FSIS Directive 10,625.1, dated 2/26/86
MPI Bulletin 83-26, dated 5/10/83
MPI Regulations, Sections 312.10 and 381.112
MPI Manual, Part 23A

V. FORMS

The following will appear in their abbreviated form in this directive:

FSIS Form 10,530-1 Monitoring Residue Program
FSIS Form 9770-2 Import Residue Program
FSIS Form 10,000-2 Laboratory Report
FSIS Form 10,600-1 Chemical Laboratory Analysis
FSIS Form 7355-1 Sample Seal (roll tape with die-out seals)

VI. BACKGROUND

Until now, no unified system has existed to prevent tampering with samples submitted to laboratories for analysis or held for incubation in the establishment. (Agar plates (petri dishes) and incubators used in the STOP, CAST, and SIFT tests are included in this directive.) Regular,

systematic use of sample seals is designed to protect against otherwise undetected opportunities for tampering with samples. The time period beginning when the sample leaves the inspector's control and ending when the sample is received at the laboratory or other location, or during incubation in the establishment, provides the greatest opportunity for tampering. Use of sample seals should minimize tampering risks and ensure that:

A. Sample integrity and identity are maintained; and

B. Subsequent analytical findings are reliably and accurately associated with the actual sample submitted.

VII. DESIGNATION OF LABORATORIES

Laboratory when used in this directive refers to:

A. The three Field Service Laboratories (Athens, GA, St. Louis, MO, and Alameda, CA):

B. The Beltsville National Laboratories, Beltsville, MD;

C. The FSIS Contract Laboratories; and

D. Accredited laboratories.

VIII. SEALING PROCEDURES

A. Seal the immediate package containing the sample (not the outside shipping container) so that the package cannot be opened unless the seal is broken.

B. If the surface of the immediate container is of a construction or condition that prevents a sample seal from adhering (waxed, frosted, or sweating surface), insert the immediate container in another container that a sample seal will adhere to.

C. For small size samples:

1. Place the sample in a plastic bag, twist top of bag, fold, and close with rubber band. Place this bag into a second bag for added protection; and

2. Close the second bag in the same manner and affix a sample seal around the rubber band at the top of the bag so that the bag cannot be opened or the seal removed without evidence of damage.

D. For larger packages:

1. After wrapping and/or preparing the package to withstand handling, start at the top of the package and place an unbroken

strip of suitable gummed tape completely around the package and continue to overlap the starting point of the tape at the top of the package. Where needed, protect package labeling in a suitable manner to ensure against defacing when the tape is removed;

2. Place a second unbroken strip of suitable gummed tape at a 90 degree angle to the first strip and wrap completely around the package. Overlap the second strip in the same place as the first; and

3. Apply the sample seal firmly and securely at the junction where the tape(s) meet and overlap. Press the entire surface of the seal to ensure proper adherence, making sure that the seal cannot be removed without becoming damaged.

E. For SIFT, CAST, and STOP tests or swab tests which require the use of agar plates (perti dishes) and/or incubators in the establishment:

1. Apply the sample seal to individual agar plates or stacks of plates incubating in the establishment very carefully to avoid tipping or dislodging the disk or swab; or

2. Avoid handling the test plates by using sample seal(s) to secure the incubator doors or other enclosed area, such as a desk drawer, where the plates are being incubated. Apply the security seal(s) firmly and securely at both junctions of the incubator door(s).

IX. RESPONSIBILITIES

Inspection program employees are responsible for maintaining sample identity and integrity. Samples collected by inspection program employees may serve as indicators of regulatory compliance and/or be used for official decisionmaking. Samples collected and submitted for analysis or examination must be representative of the lot(s) of product in question.

A. Inspection Program Employee.

1. Signs, dates, and affixes a sample seal to each sample submitted to Program laboratories for analysis or the test agar plates (petri dishes) held for incubation in the establishment (or to incubator doors).

2. Completes the proper FSIS form (10,530-1, 9770-2, 10,000-2, or 10,600-1) to accompany a sample shipped to a Program laboratory.

3. Writes the serial number (printed in the upper right hand corner) of the form on the corresponding sample seal (on line

marked Sample No. -----, to avoid sample and paperwork mixup.

4. Uses the security seal as an in-plant or between-plant measure as necessary to maintain the security and integrity of both samples and products.

5. Takes appropriate action when the original sample seal(s) is reported or discovered to be broken, missing, or is suspected of having been tampered with.

6. Takes appropriate action after receiving returned lab forms with a condition code indicating a broken, missing or unsigned seal (see IX. B. 1. below).

7. Reports evidence of real or suspected tampering involving security seals to his/her supervisor.

8. Maintains security seals under control as required by FSIS.

B. Laboratory.

1. Records, when applicable, on Form, 10,530-1, in block entitled "condition", on Form 9770-2 in block 29, on Form 10,000-2 in block 22, or on Form 10,600-1 block 20, a condition code as follows:

(35) Sample seal broken
(36) Sample seal missing
(37) Sample seal unsigned

2. Analyzes the sample without retention or further consideration of the security seal.

C. Inspection Program Supervisor.

1. Reviews the use and control of sample seals during routine establishment visits.

2. Takes action to correct any problems identified.

D. Regional Offices and Import Field Offices.

Furnish sample seals as requested by Inspection Program Personnel.

H. Russell Cross
Administrator

Attachments
1 FSIS Form 10,000-2 (Reference hard copy of this directive) 2 FSIS

Form 10,600-1 (Reference hard copy of this directive) 3 FSIS Form 7355-1 (Reference hard copy of this directive) 4 FSIS Form 10,530-1 (Reference hard copy of this directive) 5 FSIS Form 9770-2 (Reference hard copy of this directive)